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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/549,546	09/14/2005	Martine Barth	11123.0101USWO	1427

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EXAMINER

MURRAY, JEFFREY H

ART UNIT	PAPER NUMBER
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1624

MAIL DATE	DELIVERY MODE
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07/24/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/549,546	Applicant(s) BARTH ET AL.	
	Examiner Jeffrey H. Murray	Art Unit 1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 June 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9 is/are pending in the application.
- 4a) Of the above claim(s) 4-6, 8 and 9 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3 and 7 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>9/14/2005</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION***Election/Restrictions***

1. This action is in response to a response to a restriction requirement filed on June 13, 2007. Applicants' election of Group II is acknowledged. The applicant has selected their election expressly *with* traverse. There are nine claims pending and four under consideration. Claims 4-6 and 8-9 are withdrawn from consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention. This is the first action on the merits. The application concerns some novel compounds of benzenesulfonamide type, their method of preparation and their use to obtain pharmaceutical compositions.

2. Applicant argues that the subject matter of the Groups is closely related and therefore should be examined together. This argument is found to not be persuasive. The groups should not be examined together because there is no special technical feature of the compounds of the general formula I. In looking at applicant's claims, only the common features may be considered part of the "special technical feature" in the current application. Claim 1 shows a compound of formula I with a common feature of having a substituted benzenosulfonamide. This sulfonamide can be attached to an alkyl or oxo-alkyl linker. Also attached to the linker is a cyclic amide, which may be a 6- or 7-membered piperidine or piperazine ring. The core compound was seen in the prior art as explained in the restriction requirement. WO 9807697 overcomes the special technical feature of the current application. One need not look at all the variable groups within the compound or composition because if an R group may be a multitude of atoms, or molecules, or residue groups, then it cannot be a "special technical feature" of the compound or composition.

Art Unit: 1624

Applicant may have interpreted examiner's request for a species election differently than intended. The species election for the restriction requirement is to give the Examiner a "starting point" upon where to begin the search, and is not the sole compound or composition that the applicant will have examined. If the elected species is found allowable, the Examiner will continue the search of other species within the elected Group until the entire Group is found allowable or an objection/rejection is made. Applicant's argument is not found persuasive. The restriction requirement is deemed proper and therefore made FINAL.

Priority

3. Acknowledgment is made of Applicant's claim for foreign priority. This application is a non-provisional application 10/549,546, filed September 14, 2005 and is a national stage entry of PCT/FR04/00723, filed March 24, 2004, which claims foreign priority to FR03/04530, filed April 11, 2003 and FR03/04640, filed March 25, 2003.

Specification

4. Applicant is reminded of the proper content of an Abstract of the Disclosure.

In chemical patent abstracts for compounds or compositions, the general nature of the compound or composition should be given as well as its use, *e.g.*, "The compounds are of the class of alkyl benzene sulfonyl ureas, useful as oral anti-diabetics."

Exemplification of a species could be illustrative of members of the class. For processes, the type reaction, reagents and process conditions should be stated, generally illustrated by a single example unless variations are necessary.

Art Unit: 1624

Complete revision of the content of the abstract is required on a separate sheet.

5. The disclosure is objected to because of the following informalities:

On page 6 of the Specification, lines 21-23, the R groups listed do not agree in number with the subject matter. The R groups should be listed in the singular form.

Appropriate correction is required.

6. The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any of the errors of which applicant may become aware of in the specification.

Claim Rejections - 35 USC § 112, 1st

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 1-3, and 7 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claims contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claims 1-3 and 7 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a compound of Formula I where R₁ is H, -CH₃, a halogen, or -OCH₃; R₂ is -CH₃, -Cl, or -CF₃; R₃ is H, -CH₃, -iPr, or -Cl; R₄ is -H or -CH₃; R_n is -C₁-C₃ alkyl and Y is only -CH₂CH₂-O-CH₂, does not reasonably provide

Art Unit: 1624

enablement for any of the other groups listed within the application. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to making the invention commensurate in scope with these claims.

The test of enablement is whether one skilled in the art could make and use the claimed invention from the disclosures in the application coupled with information known in the art without undue experimentation. (United States v. Teletronics Inc., 8 USPQ2d 1217 (Fed. Cir. 1988)). Whether undue experimentation is needed is not based on a single factor, but rather a conclusion reached by weighing many factors (See Ex parte Forman 230 USPQ 546 (Bd. Pat. App. & Inter. 1986) and In re Wands, 8 USPQ2d 1400 (Fed. Cir. 1988)).

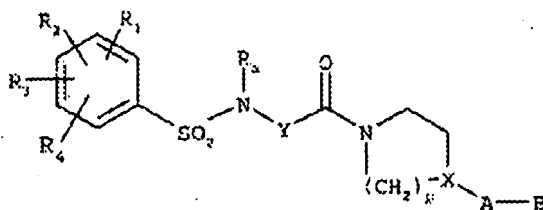
These factors include the following:

1) *Amount of guidance provided by Applicant.* While the Applicant has demonstrated within the application how to make a select number of benzenesulfonamide type compounds, the generic Claim 1 is massive, and only a small fraction of the thousands of claimed compounds are discussed, and their syntheses shown. Numerous residue groups listed within the Claims have not been synthesized or tested in any way whatsoever.

2) *Number of working examples.* Applicant has provided a miniscule fraction of the thousands of compounds that exist in the broad Claim 1.

3) *Scope of the claims.* The scope of the claims involve all of the thousands of compounds of general formula (I) where p is 2, X is N and the Y linker is -CH₂CH₂-O-CH₂:

Art Unit: 1624



Thus, the scope of claims is very broad.

4) *Nature of the invention.* The present invention concerns novel compounds of benzenesulfonamide type, their method of preparation and their use to obtain pharmaceutical compositions.

5) *Level of skill in the art.* The artisan using Applicants invention would be a physician with a M.D. degree, and having several years of experience.

MPEP §2164.01 (a) states, "A conclusion of lack of enablement means that, based on the evidence regarding each of the above factors, the specification, at the time the application was filed, would not have taught one skilled in the art how to make and/or use the full scope of the claimed invention without undue experimentation. *In re Wright*, 999 F.2d 1557,1562, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993)." That conclusion is clearly justified here that Applicant is not enabled for making these compounds or compositions or treating the diseases mentioned.

Claim Rejections - 35 USC § 112, 2nd

9. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Art Unit: 1624

10. Claim 7 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 7 recites the phrase "its pharmaceutically acceptable addition salts..." No definition is given within the claims or the specification as to what is meant by "a pharmaceutically acceptable addition salt." No new matter allowed. Appropriate correction is necessary.

Conclusion

22. Claims 1-3, and 7 are rejected.

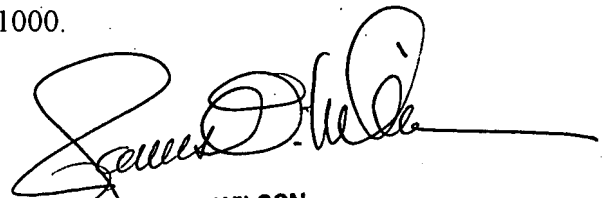
23. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey H. Murray whose telephone number is 571-272-9023. The examiner can normally be reached on Mon-Thurs 7:30-6pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisors, James O. Wilson can be reached at 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1624

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JHM



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